

REMARKS

I. Introduction

The final Office Action of April 16, 2007 has been reviewed and the Examiner's comments carefully considered. The rejoining of claims 17-25 is acknowledged. This Amendment amends independent claims 1, 21, 26, and 83, cancels dependent claims 2, 22, 24, 84, and adds new claims 116-117 which depend ultimately from independent claim 21. No new matter is present in new claims 116-117 as support for these claims is found in paragraphs [0217]-[0218] of the specification and FIGS. 29-31 of the drawings. Claims 99-115 are also cancelled in the foregoing to avoid any possible issues under 35 U.S.C. §112, fourth paragraph. This is likewise the case with cancelled claims 2 and 84. The subject matter of cancelled claim 22 is now present in independent claim 21. Claim 23 stands amended for antecedent basis reasons.

II. 35 U.S.C. § 102(b) Rejections

Claims 1-6, 8-10, 12-16, 26-30, 36-40, 42, 83-88, 90-113, and 115 stand rejected under 35 U.S.C. § 102(b) for anticipation by United States Patent No. 5,584,671 to Schweitzer, Jr. et al. ("Schweitzer"). Applicants respectfully traverse these rejections for the following reasons.

Independent claim 1 stands amended to clarify the issues raised in paragraph 8 of the final Office Action. Specifically, the fluid control device stands clarified as being operatively associated with the multi-position valve of the fluid path set and disposed downstream of the pump device and comprising a valve actuator to automatically operate the multi-position valve. Independent claims 26 and 83 stand amended in a similar clarifying manner to independent claim 1, with claim 26 indicating that the valve actuator is operatively associated with the multi-position valve and is disposed downstream of the pump device and to include certain additional language to conform to that used in independent claim 1.

Schweitzer is directed to a fluid delivery system including a pump (16) and a fluid delivery set (11). The fluid delivery set (11) includes a stop cock valve (19) operatively coupled to a valve actuation unit (14). The fluid delivery set (11) further includes a pair of inlet tubes

(17, 18) which are connected to fluid containers, an outlet tube (21), and a patient connector tube (25).

It is respectfully submitted that the clarifications made to independent claims 1, 26, and 83 distinguish over teachings of Schweitzer taken alone or in view of Duchon. These clarifications indicate that: (1) the fluid control device is disposed downstream of the pump device and (2) comprises a valve actuator that automatically operates the multi-position valve. It is noted that claim 26 is itself directed to the fluid control module and the foregoing clarifications differ slightly in form as a result. Schweitzer does not anticipate or render obvious these clarifications for the simple reason that no structure or device exists between pump (16) and patient connector tube (25) that could in any way isolate, selectively or otherwise, a pump device from a patient as described in independent claims 1, 26, and 83. There is simply no such structure present downstream of pump (16). In contrast, stop cock valve (19) identified in the final Office Action as a multi-position valve is located far upstream from pump (16) and, therefore, is not located in the position described in independent claims 1, 26, and 83 (i.e., downstream of the pump device). As a result of the positioning of stop cock valve (19) in fluid delivery set (11), this valve is not able to isolate pump (16) from a patient (associated with patient connector tube (25)) in the manner described in these claims, namely to provide a “sharp bolus” of injection fluid to the patient. In contrast to the argument proposed in paragraphs 3 and 8 of the final Office Action, the Schweitzer pump (16) will continue to operate even after the stop cock valve (19) is manually operated to a closed position until fluid in outlet tube (21) is exhausted resulting in continuously diminishing fluid flow to the patient via patient connector tube (25). This is the antithesis of a “sharp bolus” of injection fluid.

A quick inspection of FIG. 1 of Schweitzer will confirm Applicants’ foregoing contentions regarding stop cock valve (19). Stop cock valve (19) is located to provide fluid communication between one of the pair of inlet tubes (17 or 18) and an outlet tube (21) of fluid delivery set (11) as set forth at column 8, lines 1-21 of Schweitzer. Accordingly, while manual stop cock valve (19) in the Schweitzer fluid delivery set (11) may be able to isolate one of the pair of inlet tubes (17, 18) from outlet tube (21), it is not located in the position described in independent claims 1, 26, and 83 (i.e., downstream of the pump device) and as a result cannot operate to isolate pump (16) from a patient (via patient connector tube (25)) in the manner

described in independent claims 1, 26, and 83 which provides a “sharp bolus” of injection fluid to the patient.

Moreover, stop cock valve (19) is manually-operated as opposed to the claimed automatically-operated multi-position valve. Accordingly, independent claims 1, 26, and 83 are respectfully submitted as distinguishing over Schweitzer and reconsideration of the rejections of independent claims 1, 26, and 83 is respectfully requested.

United States Patent No. 6,099,502 to Duchon et al. (“Duchon”) and United States Patent No. 5,057,081 to Sunderland are again cited in the final Office Action. It is clear that Sunderland does not overcome the foregoing deficiencies with Schweitzer. With respect to Duchon, paragraph 8 of the final Office Action appears to intimate that stopcock valve (34) disclosed by Duchon may meet the requirements of independent claims 1, 26, and 83 with respect to a multi-position valve and valve actuator. However, stopcock valve (34) is manually-operated in just the same manner as stop cock valve (19) disclosed by Schweitzer and, therefore, has the same deficiencies as Schweitzer set forth hereinabove. Further, check valve (24) disclosed by Duchon located between radiographic material bottle (22) and syringe body (18) fails to meet either of the clarifications made to independent claims 1, 26, and 83. First, check valve (24) is not disposed downstream of the syringe pump device (18) and, second, is not an automatically operated valve. Accordingly, these two valves in Duchon do not cure the previously discussed deficiencies of Schweitzer. Reconsideration of the rejection of independent claims 1, 26, and 83 is respectfully requested.

Claims 3-16 and 27-49 ultimately depend from and add further limitations to independent claims 1 and 26, respectively, and are allowable for the reasons discussed hereinabove in connection with independent claims 1 and 26. Likewise, claims 85-98 ultimately depend from and add further limitations to independent claim 83 and are allowable for the reasons discussed hereinabove in connection with independent claims 83.

III. 35 U.S.C. § 103 Rejections

Claims 7, 11, 21-25, 41, 43-49, 89, and 114 stand rejected under 35 U.S.C. § 103(a) for obviousness over Schweitzer in view of Duchon. Claims 31-35, 17-20, and 104-109 stand rejected under 35 U.S.C. § 103(a) for obviousness over Schweitzer in view of Sunderland. It is noted that claims 7, 11, 41, 43-49, and 89 ultimately depend from and add further limitations

to one of independent claims 1, 26, and 83 and have been addressed in the foregoing and are believed to be in condition for allowance.

With respect to claims 21-25, independent claim 21 stands amended to recite that the closure member is movable from a closed position wherein the closure member secures the medical tubing in operative association with the air column detector, and an open position allowing the medical tubing to be disassociated from the air column detector. The closure member is indicated as being biased to the open position.

Duchon in FIG. 19 discloses an air column detector (552) that defines a groove (590, FIG. 18), which provides a friction fit with a fluid line (588). The tubing of fluid line (588) snaps into groove (590) to secure it therein. Manually-operated holders (627, 628) are manually-operated by the attending personnel to swing down over fluid line (588) to secure it in place (FIG. 19). While, holders (627, 628) are used to hold fluid line (588) in place in groove (590) it is clear that these manually-operated structures are not in any way “biased” in the manner set forth in independent claim 21 with respect to the closure member. A friction fit is used to hold holders (627, 628) in the engaged position depicted in FIG. 19 of Duchon but holders (627, 628) are not “biased” either into or out of the engaged position depicted in FIG. 19. Accordingly, Duchon fails to teach or suggest the biased closure member set forth in independent claim 21.

New claims 116-117 depend from independent claim 21 and distinguish over Duchon for the foregoing reasons. Additionally, it is noted that the Duchon holders (627, 628) do not have an automatically releasable locking mechanism as set forth in claim 116 or a locking mechanism that may be button actuated as set forth in claim 117.

With respect to claims 31-35, it is noted that these claims ultimately depend from independent claims 26 and 83, respectively, and Sunderland does not overcome the deficiencies of Schweitzer and Duchon discussed previously. Accordingly, claims 31-35 are believed to be in condition for allowance.

Sunderland is newly cited in connection with claims 17-20. Independent claim 17 is directed to an injector system comprising a drip chamber comprising a body with a projection and a fluid level sensing mechanism. The fluid level sensing mechanism comprises a drip chamber support for supporting the drip chamber body, and a fluid level sensor associated with the drip chamber support, the drip chamber support adapted to support the drip chamber body such that the projection is operatively associated with the fluid level sensor.

In the final Office Action, it is argued in paragraph 7 that “Sunderland teaches a drip chamber for use in a peristaltic infusion device wherein the drip chamber (42) includes a body (48) with a longitudinally extending projection (37)”. Applicants direct attention to FIGS. 4-6 and, particularly, FIG. 10 of Sunderland and the following passage found at column 6, lines 54-62 of Sunderland stating:

The upper flange 26 includes an elongate and semi-circular drip chamber yoke retaining flange 36 which consists of a set of flanges and recesses which are located rearwardly of the front surface 20 of the upper flange 26 to retain the drip chamber yoke 37 in fluid tight communication with the housing assembly 12 to allow the user to clean the drip chamber recess 39 without exposing the electronics in the housing assembly 12 to the cleaning fluid.

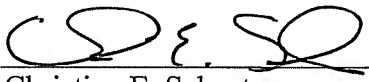
It is clear from FIGS. 4-6 and, particularly, FIG. 10 and the foregoing passage from Sunderland that the structure (drip chamber yoke 37) cited in paragraph 7 of the final Office Action as “a longitudinally extending projection” is in actually nothing more than the retaining structure (i.e., a yoke) associated with retaining flange (36) for securing drip chamber (42) in place in recess (39). Yoke (37) is **not** a part of drip chamber (42). Accordingly, Applicants respectfully submit that drip chamber (42) disclosed by Sunderland does not have the claimed “projection” and independent claim 17 cannot be anticipated by or rendered obvious over Sunderland. Schweitzer discloses a drip chamber (23) which also lacks the claimed “projection”. Therefore, independent claim 17 is respectfully submitted as distinguishing over Schweitzer taken alone or in combination with Sunderland or vice versa. Reconsideration of the rejections of claims 17-20 over Schweitzer and Sunderland and allowance of the same are respectfully requested.

Based on the foregoing amendments and remarks, reconsideration of the rejections and allowance of pending claims 1, 3-16, 26-49, 83, 85-98, 116, and 117 is respectfully requested.

IV. Conclusion

Should the Examiner have any questions regarding any of the foregoing or wish to discuss this application in further detail to advance prosecution, the Examiner is invited to contact Applicants' undersigned representative at the telephone number provided below.

Respectfully submitted,

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